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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,394	08/01/2001	Rosanne M. Crooke	ISPH-0589	4398

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EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,394

Applicant(s)

CROOKE ET AL.

Examiner

J. Douglas Schultz

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1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges the error of the previous Office action stating that 1, 2, and 4-14 were pending, when it should have stated that 1, 2, and 4-20 were pending. The examiner further acknowledges the cancellation of claims 11, and 16-20. It is pointed out that contrary to Applicant's statement of Amendment B, entered Sept. 16, 2002, that claim 3 is not amended, but was canceled in Amendment A filed June 5, 2002.

Election/Restrictions

Newly submitted claim 1 is directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Amended claim 1 introduces new subject matter in the form of two sequences that have, to date, not appeared in any claim in the instant application, and were not examined in the Office action of June 18, 2002. These sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct due to each having a unique nucleotide sequence. Furthermore, a search of newly added sequences introduced later during prosecution presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one claimed sequence. Since applicant has received an action on the merits for the originally presented invention, that is in regards to SEQ ID NO:3, this invention has been constructively elected by original presentation for prosecution on the

merits. Accordingly, those elements of claim 1 that are drawn to newly introduced sequences, i.e. SEQ ID NO 10, are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

Applicant's response filed Sept. 5, 2002 has been considered. Rejections and/or objections not reiterated from the previous office action mailed June 18, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. Furthermore, applicant's arguments with respect to claims 15-20 are noted, but are not considered as a result of applicant's cancellation or amendment of said claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (U.S. Patent Number 5,968,749), and Chang et al. (U.S. Patent Number 5,484,727) in view of Baracchini et al., (U.S. Patent Number 5,801,154), for the same reasons of record as set forth in the Office action mailed Sept. 16, 2002.

The claims are drawn to antisense compounds 8-50 nucleobases in length that target and inhibit the expression of acyl coenzyme A cholesterol acyltransferase-1 (ACAT) of SEQ ID NO:3 targeted to a start codon region, a coding region, or a stop codon region, and to internucleoside, sugar, or nucleobase modifications and chimeras of said antisense compounds, and compositions providing for their *in vivo* use.

Applicant traverses the rejection of the above listed claims on the grounds that neither of the Chang et al. patents teach or suggest actual antisense sequences, or successfully demonstrate antisense inhibition of ACAT, and only generally discuss using antisense as a tool to inhibit. Furthermore Applicant argues that nowhere does either Chang et al. patent disclose any sequences 8 to 50 nucleotides long targeted to the instantly claimed regions of SEQ ID NO:3.

Applicant's arguments filed September 16, 2002 have been fully considered but they are not persuasive. Contrary to Applicant's assertion, Chang et al. specifically claim the oligonucleotide compounds for the inhibition of ACAT ('749 patent, claim 2). Regarding Applicant's arguments that neither of the Chang et al. patents don't disclose actual sequences, or demonstrate the successful use of antisense sequences, and that they only generally discuss antisense inhibition, Applicant appears to be suggesting that the antisense inhibition as taught by Chang et al. is not enabled. However, an issued U.S. Patent is considered to be enabled, in the absence of evidence to the contrary. Applicant has provided no such evidence. Furthermore,

Chang et al. in both patents at Col. 5 lines 25-28 specifically disclose the targeting of regions identical to that of Applicant's claim 1, that is, the coding and start codon regions. While it is true that Chang et al. do not teach compounds 8 to 50 nucleotides in length, Chang et al. were not relied upon for this. Baracchini et al. specifically teach the use of antisense compounds 8 to 50 nucleotides in length to target and inhibit genes. Thus, the combination of the two references teach all the elements; in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Accordingly, for the reasons given above, the rejection of the above claims is proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
November 29, 2002



ANDREW WANG
SUPERVISORY PATENT EXAMINER
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